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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,473	01/21/2004	John C. Rueter	P0011409.00	4388

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EXAMINER	
GEDEON, BRIAN T	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,473	RUETER, JOHN C.	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This action is in response to the amendment after non-final filed 21 February 2008.

Oath/Declaration

2. The objection made to oath/declaration in the previous Office action is withdrawn in view of Applicant's arguments.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10 and 12-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear and indefinite how the invention detects a need for an added safety factor in response to a perceived increase in the pacing threshold if there is an absence of a pacing threshold test. The Examiner considers that since the invention monitors for indications of an increase in the pacing threshold, a test indicating an increase in threshold (i.e., a threshold test) is necessarily performed.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Sloman et al. (EP 1 136 098 A2). This rejection is maintained from the previous Office action.

In regard to claim 11, Sloman et al. describes an implantable medical device 10 comprising: a pulse generator 70 and 72, col 7 lines 40-45, for delivering pacing pulses; at least one electrode 26, 27, and 28, see fig. 1 and col 6 lines 5-8, in electrical communication with the pulse generator for delivering the pacing pulses to cardiac tissue; and a microprocessor 60, col 7lines 17-18, for controlling the pulse generator, receiving sensed data from the at least one electrode, wherein the sensed data includes an indicator, col 17 line 28, of increased pacing threshold, and increasing a safety factor, col 17 lines 19-22, used for setting the pacing pulse energy delivered by the pulse generator when the indicator of increased pacing threshold is detected.

7. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Schloss (6,456,882). This rejection is maintained from the previous Office action.

In regard to claim 11, Schloss describes an implantable medical device 700 comprising: a pulse generator 80, for delivering pacing pulses; at least one electrode 75 and 77, in electrical communication with the pulse generator for delivering the pacing

pulses to cardiac tissue; and a microprocessor 22 for controlling the pulse generator, receiving sensed data from the at least one electrode, wherein the sensed data includes an indicator, col 12 lines 27-30, of increased pacing threshold, and increasing a safety factor, col 12 lines 25-27, used for setting the pacing pulse energy delivered by the pulse generator when the indicator of increased pacing threshold is detected, also see figure 3.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 6-10, 12, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sloman et al. (EP 1 136 098 A2).

In regard to claims 1 and 12, Sloman et al. describes an implantable medical device 10 comprising: a pulse generator 70 and 72, col 7 lines 40-45, for delivering pacing pulses; at least one electrode 26, 27, and 28, see fig. 1 and col 6 lines 5-8, in electrical communication with the pulse generator for delivering the pacing pulses to cardiac tissue; and a microprocessor 60, col 7lines 17-18, for controlling the pulse generator, receiving sensed data from the at least one electrode, wherein the sensed data includes an indicator, col 17 line 28, of increased pacing threshold, and increasing a safety factor, col 17 lines 19-22, used for setting the pacing pulse energy delivered by

the pulse generator when the indicator of increased pacing threshold is detected. However, Sloman et al. do not teach indicating an increased pacing threshold in the absence of a pacing threshold. In view that Sloman et al. teach that it is known in the art to add a safety factor/margin to the pacing pulse in the event that an increase in pacing threshold is perceived, it is considered to be obvious to one of ordinary skill in the art at the time the invention was made to add a safety factor whenever an increase in pacing threshold is sensed.

In regard to claims 6-10 and 16-20, Sloman et al. have an impedance sensor 112, an arrhythmia detector, col 11 lines 25-47, a refractory period detector, col 8 lines 1-2, and/or change in pacing/stimulation modes, col 12 lines 4-15.

10. Claims 2-5 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sloman et al. (EP 1 136 098 A2) in view of Schloss (6,456,882).

In regard to claims 2-5 and 13-15, Sloman et al. substantially describe the invention as claimed except for the setting time interval and restoring safety factors to a programmed variable. Schloss teaches setting a time interval during which the increased safety factor is maintained; and restoring the safety factor to a programmed value after the time interval has expired, col 3 lines 42-47, and setting a time interval during which the increased safety factor is maintained; and restoring the safety factor to a programmed value after the time interval has expired, col 3 lines 37-41. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Sloman et al. with the teaching of Schloss in order to

determine if the safety margin adjustment criteria has been met, and that excess energy is not expended if deemed not necessary by having a high safety margin.

11. Claims 1-5 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schloss (6,456,882).

In regard to claims 1 and 12, Schloss describes an implantable medical device 700 comprising: a pulse generator 80, for delivering pacing pulses; at least one electrode 75 and 77, in electrical communication with the pulse generator for delivering the pacing pulses to cardiac tissue; and a microprocessor 22 for controlling the pulse generator, receiving sensed data from the at least one electrode, wherein the sensed data includes an indicator, col 12 lines 27-30, of increased pacing threshold, and increasing a safety factor, col 12 lines 25-27, used for setting the pacing pulse energy delivered by the pulse generator when the indicator of increased pacing threshold is detected, also see figure 3. However, Schloss et al. do not teach indicating an increased pacing threshold in the absence of a pacing threshold. In view that Schloss et al. teach that it is known in the art to add a safety factor/margin to the pacing pulse in the event that an increase in pacing threshold is perceived, it is considered to be obvious to one of ordinary skill in the art at the time the invention was made to add a safety factor whenever an increase in pacing threshold is sensed.

In regard to claims 2, 3, 13, and 14, setting a time interval during which the increased safety factor is maintained; and restoring the safety factor to a programmed value after the time interval has expired, col 3 lines 42-47.

In regard to claims, 4, 5, and 15, setting a time interval during which the increased safety factor is maintained; and restoring the safety factor to a programmed value after the time interval has expired, col 3 lines 37-41.

12. Claims 6-10 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schloss (6,456,882) in view of Sloman et al. (EP 1 136 098 A2).

In regard to claims 6-10 and 16-20, Schloss substantially describes the invention as claimed except for the indicators of increased pacing threshold. Sloman et al. have an impedance sensor 112, an arrhythmia detector, col 11 lines 25-47, a refractory period detector, col 8 lines 1-2, and/or change in pacing/stimulation modes, col 12 lines 4-15. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Schloss with the teachings of Sloman et al. since Sloman et al. discloses means and methods for detecting various indicators indicating an increased threshold.

Response to Arguments

13. Applicant's arguments with respect to claims 1-10 and 12-20 have been considered but are moot in view of the new ground(s) of rejection. The rejections are presented above and reiterated to address the newly added limitations.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

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